

## REMARKS

With the proposed claim amendments submitted herein, claims 1-3, 5-6, and 15-20 are currently pending in the instant application. Claims 35-37 have been cancelled herein, and Applicant reserves the right to prosecute that subject matter, as well as the originally presented claims, in continuing applications.

Claims 1-3 have been amended to recite an autoimmune or inflammatory disorder "selected from the group consisting of psoriasis, multiple sclerosis and rheumatoid arthritis." Support for this amendment can be found throughout the specification and in the claims as originally filed. For example, support for this amendment can be found at least at page 20, lines 4-8, and at page 20, lines 28-30, and in original claims 9 and 11. Accordingly, no new matter has been added.

Applicant notes with appreciation that the Examiner has withdrawn the outstanding obviousness-type double patenting rejections of claims 1-3, 5-6 and 15-20, as well as the outstanding rejections under 35 U.S.C. §§102(e) and 112, second paragraph, in light of the amendments filed on April 30, 2003.

### I. DOUBLE PATENTING

#### 1. Rejection under nonstatutory-type (obviousness-type) double patenting

##### U.S. Application No. 10/056,645

Claims 35-37 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent Application No. 10/056,645. Applicant notes that claims 35-37 have been cancelled herein. Accordingly, any rejection of these claims has been rendered moot and should be withdrawn.

##### U.S. Application No. 10/056,646

Claims 35-37 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent Application No. 10/056,645. Applicant notes that claims 35-37 have been cancelled herein. Accordingly, any rejection of these claims has been rendered moot and should be withdrawn.

U.S. Application No. 10/056,608

Claims 35-37 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent Application No. 10/056,608. Applicant notes that claims 35-37 have been cancelled herein. Accordingly, any rejection of these claims has been rendered moot and should be withdrawn.

U.S. Application No. 10/056,288

Claims 35-37 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-99 of U.S. Patent Application No. 10/056,288. Applicant notes that claims 35-37 have been cancelled herein. Accordingly, any rejection of these claims has been rendered moot and should be withdrawn.

## **II. CLAIM REJECTIONS**

### **1. Rejection of claims 35-37 under 35 U.S.C. § 112, first paragraph**

Claims 35-37 stand rejected under 35 U.S.C. § 112, first paragraph, as “failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.” (Office Action, p. 6). Applicant notes that claims 35-37 have been cancelled herein. Thus, any rejection of these claims has been rendered moot and should be withdrawn.

### **2. Rejection of claims 1-3, 6, 11, 15-20 and 35-37 under 35 U.S.C. § 112, second paragraph**

Claims 1-3, 6, 11, 15-20 and 35-37 stand rejected under 35 U.S.C. § 112, second paragraph.

With regard to claims 1-3, 6, 11 and 15-20, the Examiner has asserted that the term “said mammal,” as recited in line 6 of independent claims 1, 2 and 3 lacks sufficient antecedent basis. Applicant traverses, as claims 1-3 have been amended to replace the term “said mammal” with “said human.”

With regard to claim 36, the Examiner has asserted that the expression “therapeutically insignificant lipid-lowering effect” is a relative term that renders the claim indefinite. With regard to claim 37, the Examiner has asserted that it is not clear what compound would be considered “capable of measurable HMG-CoA reductase inhibition and inhibition of MHC Class II expression,” as recited by claim 37.

Applicant notes that claims 35-37 have been cancelled herein. Thus, any rejection of these claims has been rendered moot and should be withdrawn. Accordingly, Applicant requests that the Examiner withdraw this rejection of claims 1-3, 6, 11, 15-20 and 35-37.

**3. Rejection of claims 1-3, 6, 11, 15-20 and 35 and 37 under 35 U.S.C. § 102(b)**

Claims 1-3, 6, 11, 15-16, 18-20 and 35 and 37 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Hommel *et al.*, Diabetologia 35(5):447-51 (1992) ("Hommel"). The Examiner has also rejected claims 1-3, 6, 11, 15-20 and 35 and 37 under 35 U.S.C. § 102(b) as being anticipated by Driscoll *et al.*, Circulation 95:1126-31 (1997) ("Driscoll"). Claims 1-3, 6, 11, 15, 20, 35 and 37 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent Application No. EP 0 482 498 to Pan *et al.* ("Pan"). According to the Examiner, Hommel discloses methods of administering simvastatin to Type I diabetic patients, Driscoll discloses a method of administering simvastatin to atherosclerotic patients, and Pan discloses use of HMG CoA reductase inhibitors, such as lovastatin or pravastatin, in treating Type I or Type II diabetic patients. (Office Action, p. 11).

Claims 1-3 and their respective dependent claims (including claims 6, 11 and 15-20) have been amended to delete reference to diabetes or atherosclerosis. Applicant reserves the right to prosecute the cancelled subject matter in related applications. Claims 1-3 (and the claims that depend therefrom) recite methods of achieving MHC-class II-mediated immunomodulation, immunosuppression or anti-inflammatory effect in humans with psoriasis, multiple sclerosis, or rheumatoid arthritis. Thus, the pending claims, *i.e.*, claims 1-3, 6, 11 and 15-20, are not directed to methods of administering a statin to patients suffering from Type I diabetes or atherosclerosis.

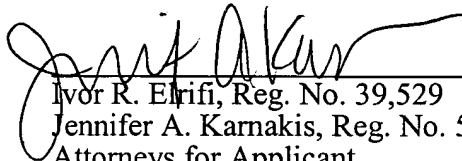
Applicant notes that claims 35-37 have been cancelled herein. Thus, any rejection of these claims has been rendered moot and should be withdrawn.

Because Hommel, Driscoll and Pan fail to disclose or suggest treatment of psoriasis, multiple sclerosis, or rheumatoid arthritis, those references cannot destroy novelty. Thus, this rejection should be withdrawn.

### CONCLUSION

On the basis of the foregoing amendments and arguments, Applicant submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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